NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Diseases Laboratories at the Boston University Medical Center

Working Group of the Advisory Committee to the Director, NIH

Minutes of Public Meeting
March 13, 2008

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

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[*Note*: Additional information about this Blue Ribbon Panel can be found at: http://www.nih.gov/about/director/acd/index.htm.]

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The National Institutes of Health (NIH) Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (Blue Ribbon Panel), a working group of the Advisory Committee to the NIH Director (ACD), convened for its first meeting on March 13, 2008. The Panel meeting was on the NIH campus, Building 1, Wilson Hall, Bethesda, Maryland. Dr. Adel Mahmoud (Chair) presided. In accordance with Public Law 92-463, the meeting was open to the public (8:30 a.m. until 2:15 p.m.). Notice of this meeting was published in the *Federal Register* on March 11, 2008 (73 FR 13006). Topics covered at this meeting included background on overarching aims and the scope of relevant research; an overview of Federal, State, and City of Boston municipal requirements; an overview of the legal proceedings to date; an overview of draft supplementary environmental risk assessments; and public comment.[1]

Blue Ribbon Panel Members in Attendance

Chairman: Adel Mahmoud, MD, PhD, Princeton University
Donald S. Burke, MD, University of Pittsburgh Medical School
Stephen Eubank, PhD, Virginia Polytechnic Institute and State University
Vicki S. Freimuth, PhD, University of Georgia
George Friedman-Jiménez, MD, Bellevue Hospital Center
Margaret A. Hamburg, MD, Nuclear Threat Initiative
Karen A. Holbrook, PhD, University of South Florida
Dennis L. Kasper, MD, Harvard Medical School and Brigham and Women's Hospital
W. Ian Lipkin, MD, Northeast Biodefense Center and Columbia University
Mary E. Northridge, PhD, MPH, Columbia University and *American Journal of Public Health*
Jean Patterson, PhD, Southwest Foundation for Biomedical Research
Samuel L. Stanley, Jr., MD, Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research and Washington University in St. Louis
Wayne Thomann, DrPH, Duke University/Duke University Medical Center

Ex Officio Members

Steven P. Bennett, PhD, U.S. Department of Homeland Security
Peter Highnam, PhD, U.S. Department of Health and Human Services (HHS)
Rima F. Khabbaz, MD, Centers for Disease Control and Prevention (CDC)

Executive Secretary to BRP

Amy P. Patterson, MD, Office of the Director (OD), NIH

Speakers

Deerin Babb-Brott, Massachusetts Environmental Policy Act Office
M. Anita Barry, MD, MPH, Boston Public Health Commission
Gigi Kwik Gronvall, PhD, University of Pittsburgh Medical Center
Seth D. Jaffe, JD, MPP, Foley Hoag LLP
Mark S. Klempner, MD, BU NEIDL

[1] The Blue Ribbon Panel is a Working Group of the Advisory Committee to the Director, NIH. Any recommendations described in these minutes should not be considered as final or accepted by the ACD or the NIH Director.

Michael G. Kurilla, MD, PhD, National Institute of Allergy and Infectious Diseases, NIH
David W. Lankford, JD, Office of the General Counsel, NIH
Mary E. Northridge, PhD, MPH, Columbia University and *American Journal of Public Health*
Gary Smith, DPhil, University of Pennsylvania School of Veterinary Medicine
Roger Swartz, JD, Boston Public Health Commission
Daniel Wheeland, Office of Research Facilities Development and Operations, NIH
Deborah E. Wilson, DrPH, CBSP, Office of Research Services, NIH
Elias Zerhouni, MD, NIH Director

Attachments

Attachment I contains lists of Blue Ribbon Panel members and speakers. Attachment II is a list of abbreviations and acronyms used in this document.

I. Call to Order/Dr. Mahmoud

Dr. Mahmoud, Chair of the Blue Ribbon Panel (BRP), called the meeting to order at 8:30 a.m. on March 13, 2008.

II. Opening Remarks and Charge

Presenter: Elias Zerhouni, MD, Director, NIH

Dr. Zerhouni welcomed the BRP members and attendees to the inaugural meeting of the Panel, noting that the issues to be discussed go beyond the risk assessment of the Boston University (BU) laboratory to include public policy and perception. He provided background about the discussions and decisions regarding biodefense research supported by the NIH. He noted that these discussions included the overarching question of whether biodefense should be managed similarly to nuclear defense or whether an open architecture that relies directly on the talent pool of universities should be used, and that after an extensive debate, the NIH decided in 2002 that the most effective strategy would be to create an open system that utilizes the best scientists in labs that are distributed regionally.

The National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University Medical Center is one of two National Biocontainment Laboratories (NBLs) that, along with 13 Regional Biocontainment Laboratories (RBLs) are elements of a comprehensive infrastructure. This system also includes 10 Regional Centers of Excellence (RCEs) for Biodefense and Emerging Infectious Diseases and 4 new NIH facilities. The RCEs provide resources and communication systems that can be mobilized rapidly and can be coordinated in response to events. The Cooperative Centers for Translational Research on Human Immunology and Biodefense, also part of this architecture, will conduct research on human immune responses against infectious pathogens and on the translational pathways. The expended Vaccine and Treatment Evaluation Units also are part of this operation.

The NIH continues to support an array of training in biosafety and biocontainment to ensure that the research staff has the necessary tools and knowledge to conduct biomedical and biodefense research safely. Training support mechanisms include the National Biosafety and Biocontainment Training Program—a component of the RCEs—and National Institute of Allergy and Infectious Diseases (NIAID) Institutional Training Grants. Through training and in other ways, the underlying principles of all NIH work in this area are to ensure maximum safety and to be able to assure the public and researchers that the research environment is safe.

Dr. Zerhouni further noted that the construction of the NEIDL followed the requirements of the National Environmental Policy Act (NEPA), which required extensive analyses regarding the siting of the facility and assessment of whether the conduct of the research in this setting would pose any undue risk to the

surrounding community. The NEPA process is transparent and entails extensive review and comment with multiple appeals processes.

Dr. Zerhouni pledged NIH support to the BRP for additional expertise when needed. He encouraged BRP members to express their views openly and honestly, noted that an effective national policy would result from an honest exchange of ideas and expertise, and stated that there are no foregone conclusions. Dr. Zerhouni underlined the importance of coming to the best possible conclusions for the U.S. public and reiterated the need for the BRP to give its advice openly and for its deliberations to be done right, even if this adds time to the process.

The BRP reports to the ACD, an advisory body composed of two-thirds scientists and one-third public members. Recommendations from the BRP will be made at public ACD meetings and will be discussed with ACD members, with a final set of recommendations forwarded directly from the ACD to Dr. Zerhouni.

III. Overview and Purpose of the Meeting

Presenter: Dr. Adel Mahmoud, MD, PhD, Chair, NIH Blue Ribbon Panel

Members of the BRP introduced themselves and described the expertise they bring to the BRP, which includes infectious diseases, public health, epidemiology, risk assessment, infectious disease modeling, risk communications, biosafety, bioethics, and environmental justice (EJ). Dr. Mahmoud noted that Drs. Lewis, Murray, and Robson were unable to attend this meeting.

Dr. Mahmoud stated that the charge to the BRP is to provide scientific and technical advice to the NIH regarding the construction and operation of an NBL at the BU Medical Center. The BRP will provide independent scientific advice regarding the scope of any additional risk assessments that might be necessary and how to engage in effective risk communication, being especially mindful of issues related to NEPA requirements, EJ, and community relations.

Dr. Mahmoud noted that the BRP is a working group of the ACD, which means that its recommendations will be conveyed to the full ACD in public session, and that the ACD's final recommendations on this issue would be conveyed to the NIH Director.

The specific tasks of the BRP will be to:

- Review judicial materials and requests and public concerns
- Consult with technical experts, including the National Research Council (NRC) committee
- Evaluate the adequacy of the scenarios, organisms, methodologies, and assumptions in the existing supplementary risk assessments
- Propose additional risk assessments as appropriate
- Provide ongoing advice regarding the conduct of risk assessment studies
- Advise on the final report

Dr. Mahmoud also noted that BRP members were provided copies of the public comments submitted with regard to the Draft Supplementary Risk Assessments and Site Suitability Analyses (DSRASSA) and that members of the public would have an opportunity at this meeting to make brief oral remarks. He also acknowledged the interest of the press in this meeting.

IV. NIH Biodefense and Emerging Infectious Diseases: Strategic Overview

Presenter: Michael G. Kurilla, MD, PhD, NIAID, NIH

To place the issues surrounding operation of the NEIDL within the context of NIAID programmatic efforts, Dr. Kurilla presented a high-level strategic overview of NIAID biodefense programs. Dr. Kurilla oversees the extramural construction program, which operates similarly to the process of awarding research grants.

Dr. Kurilla summarized a number of Homeland Security Presidential Directives (HSPDs) that have been issued in the aftermath of the events surrounding the anthrax letters. For example, HSPD-10, titled "Biodefense for the 21st Century," identified a series of four pillars upon which efforts would be concentrated—threat awareness, prevention and protection, surveillance and detection, and response and recovery. He noted that NIAID's work on preventive vaccines and therapeutics and diagnostics addressed primarily the response and recovery pillars. HSPD-18, titled "Medical Countermeasures Against Weapons of Mass Destruction," was issued in early 2007 and discussed biological threats and defined enhanced agents, emerging diseases, and prevention and therapeutic interventions. HSPD-21, issued in fall 2007 and titled "Public Health and Medical Preparedness," was an attempt to link all these activities together by establishing a national strategy for public health and overall medical preparedness. NIAID programs have evolved to respond to this directive, which is applicable to a broad array of natural and human-made public health and medical challenges.

Dr. Kurilla noted that the 2002 Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research concluded that there was a need for expansion of research capacity, both intellectual and infrastructure, and stated that research with potentially deadly Category A agents (e.g., anthrax, ebola, smallpox) must be conducted in appropriate containment facilities. Importantly, this panel noted that access to biosafety level 3 (BSL-3) and BSL-4 facilities is limited and must be expanded. Expansion of the biodefense research capacity through the NIAID extramural construction program has taken the direction of building comprehensive, state-of-the-art BSL-2, BSL-3, and BSL-4 laboratories within two NBLs, 13 RBLs, 10 RCEs (which complement the intellectual needs of this expansion), and 4 new NIH facilities (which complement the infrastructure needs). These laboratories were intended to be designed and built using the strictest Federal standards and to protect the public and the laboratory workers. Construction of these laboratories also was intended to complement and support biodefense and emerging infectious disease research as well as assist Federal, State, and local public health efforts in the event of a bioterrorism or infectious disease emergency.

Dr. Kurilla reviewed the timeline for the biocontainment construction program and noted the post-award NEIDL milestones. He showed the state of construction of the other NBL—the Galveston National Laboratory at The University of Texas Medical Branch, Galveston, Texas—and pictures of the RBLs completed to date at Colorado State University, Duke University, and the University of Pittsburgh. Currently, the BU NEIDL is 77 percent complete, with an estimated construction completion date of October 2008. After construction is complete, an ongoing commissioning process will occur that will allow laboratory work to build up from BSL-2 to BSL-3 and finally to BSL-4. Occupancy of the building is anticipated to begin in 2009.

Highlighting some of the advances that the NIAID has made recently using biocontainment laboratories, Dr. Kurilla noted the following:

- considerable progress in developing pre-pandemic avian flu vaccines; one such vaccine has been licensed
- ongoing BSL-4research utilizing murine and ferret models to test antivirals against a high-pathogenicity avian flu
- a second-generation anthrax vaccine now ready for commercial manufacture and advances toward a recombinant protective antigen
- validation of the theory that postexposure vaccination provides efficacy in addition to the protection provided by antibiotics alone

- clinical data demonstrating that both therapeutics and antitoxins are efficacious after disease develops
- development of a second-generation ebola vaccine and a multivalent platform that can cover various Ebola and Marburg viral strains; testing will require extensive nonhuman primate work at BSL-4
- further development of novel strategies, such as a ribonucleic acid interference therapeutic, which have shown effectiveness in murine and guinea pig models, will soon be conducted in nonhuman primates, requiring containment facilities to fully vet these product concepts and move them forward

V. National Emerging Infectious Diseases Laboratories at Boston University Medical Center

Presenter: Mark S. Klempner, MD, Prinipal Investigator, NEIDL, BU

Dr. Klempner discussed ongoing and potential research programs and how the NEIDL facility would support mission-critical collaborative research. He highlighted four scientific programs that are ongoing or in development and reiterated that neither bioweapons research, which is illegal, nor classified research would take place at the NEIDL. Dr. Klempner highlighted research on combating drug resistance, including using a network biology approach, stimulating hydroxyl radical formation, and creating a genomics platform. He also discussed research on avian influenza and associated lung damage, approaches to filovirus vaccines, Marburg and ebola viruses, and global and national distribution of West Nile virus, all within the context of current or planned research that would need to be conducted at the BU NEIDL.

He pointed out that antibiotic resistance is increasing in incidence, whereas few new antibacterial agents are being developed. According to CDC statistics, from 1980-2003 there was a significant increase in the rates of resistance for three bacteria that are of concern to public health officials: methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus* strains, and fluoroquinolone-resistant *Pseudomonas aeruginosa*. In addition, multidrug-resistant tuberculosis (MDR TB) and extensively drug-resistant tuberculosis (XDR TB) are spreading throughout the world. At the same time, the pipeline for new antibiotics is increasingly empty. In the 1980s, about 30 new antibiotics were approved for human use; however, in the past 5 years, only one new antibacterial agent has been approved for human use. Increasingly, patients are faced with infections for which there is only one antibiotic to which life-threatening pathogens are sensitive.

Dr. Klempner described how BU NEIDL investigators are pioneering new ways to discover better targets for new antibiotics and better ways to use combinations of drugs to combat drug-resistant bacteria, including TB. For example, Dr. James Collins and his colleagues at BU have discovered that familiar antibiotics such as penicillins, quinolones, and aminoglycosides, which were posited to kill bacteria through different pathways, actually kill bacteria through a common pathway by causing production of reactive oxygen molecules that are lethal to the bacteria. By deciphering the gene networks that operate in TB bacteria and then examining individual or combinations of drugs that inhibit growth or kill drug-resistant TB, it is proving possible to identify high-value targets for new anti-TB drugs or more effective drug combinations to combat drug resistance in general and drug resistance to TB in particular. Dr. Collins was recently awarded a highly competitive NIH Director's Pioneer Award to further his research in this critical area of antimicrobial resistance.

High-containment facilities are needed to study MDR TB and XDR TB. Although both MDR TB and XDR TB are already present in the human population, these organisms must be worked on in high-containment settings to protect those who work with them. Work with MDR TB and XDR TB require BSL-3 facilities at a minimum. Since XDR TB can be transmitted via aerosols, there is no vaccine to prevent infection, and there are no clearly proven and effective drug therapies, a strong case can be made for maximizing researcher safety by studying XDR TB at BSL-4.

Dr. Klempner highlighted the work of BU investigators Drs. Alan Fine and Darryl Cotton and their colleagues who have been on the leading edge of studying lung repair and regeneration following acute lung injury. They have discovered how bone marrow-derived stem cells can be programmed to become alveolar lining cells once they migrate to the lung. These results point to possible therapeutic innovations for acute lung injury caused by influenza and other pathogens. Since there are effective treatments and a vaccine for most circulating strains of influenza, these strains can be studied safely at BSL-2. However, avian influenza is minimally transmissible from birds to humans and even more rarely transmitted from human to human, so to protect laboratory workers, BSL-3 is required to study highly virulent avian influenza, and BSL-4 is required to study strains of influenza that are potentially more communicable.

Dr. Klempner noted that one of the high priorities of the NIAID Emerging Infectious Diseases and Biodefense Program is a multivalent vaccine against the viruses that cause hemorrhagic fever, such as ebola and Marburg viruses. Through research sponsored by the NIAID and others, two experimental platforms for effective vaccination have gained momentum. Adenoviral vectors that carry Ebola genes but do not replicate are effective in protecting nonhuman primates from Ebola infection; however, it is not known whether they are effective against Marburg virus, and because many humans have antibodies to the adenoviral vector, the potential of this vaccine candidate may be limited. Dr. Tom Geisbert, who joined the BU NEIDL faculty last year, and his collaborators have focused on a replicating vesicular stomatitis viral vector that can serve as a vaccine platform against ebola and Marburg viruses. BSL-4 laboratories are required to further these studies of vaccine protection against ebola, Marburg, and other hemorrhagic fever viruses. Studies on the pathogenesis and treatment of the hemorrhagic fever viruses as well as some of the viruses that cause encephalitis will also require BSL-4 containment.

Infectious diseases transmitted by mosquito and tick vectors—such as West Nile virus, Dengue virus, Eastern equine encephalitis virus, and some hemorrhagic fever viruses—are among the many vector-transmitted infectious diseases of public health concern; the spread of mosquito-transmitted West Nile virus across the United States is a recent example. The most successful strategies for controlling vector-transmitted infections have been to decrease or eradicate the vector (insect) or to find drugs to prevent or treat infection in the human host; however, vector elimination with compounds such as DDT carries its own perils. Dr. Horatio Friedman, a NEIDL investigator, made the recent discovery that the *Wolbachia* bacterium localizes to the stem cells of these insects and can infect a large percentage of the insects that transmit infectious diseases around the world. This finding paves the way for interrupting vector-borne diseases by rendering the insect unable to transmit the infectious disease. Preferentially shortening the lifespan of mosquitoes infected with Dengue virus, West Nile virus, or malaria by a few days would result in a dramatic reduction in possible transmission to humans. Experiments on vector-transmitted infectious diseases such as Dengue virus, chikungunya fever virus, and tick-transmitted hemorrhagic fever viruses require specialized BSL-3 and BSL-4 laboratories such as those being built at the NEIDL.

Dr. Klempner noted that one of the most important aspects of the BU NEIDL is to serve the Nation as a research resource for studies of emerging infectious diseases that require its specialized containment facilities. In addition, NEIDL leadership has placed special emphasis on facilitating collaborations with regional, national, and international scientists whose research needs to be conducted in a high-containment facility such as the NEIDL.

VI. Federal Environmental Policy Requirements Under the NEPA

Presenter: Daniel Wheeland, Director, Office of Research Facilities Development and Operations (ORF), NIH

Mr. Wheeland discussed how NEPA requirements affect the construction grant for the BU NEIDL. As the basic national charter for protection of the environment, the NEPA establishes policy, sets goals, and provides means for carrying out policy. The purpose of the NEPA is to ensure that Federal agencies understand the potential impacts of their actions, mitigate negative impacts where possible, and make informed decisions. Because the NIH, a Federal agency, is partially funding the construction of the NEIDL, the requirements of the NEPA apply to this construction.

Mr. Wheeland described two key documents developed in accordance with the NEPA. An environmental impact statement (EIS) is a written document that sets forth an assessment of how a course of action is likely to affect the environment and delineates the potential impacts of an action. In the case of the NEIDL, the NIH prepared an EIS that analyzed the potential impacts and mitigation measures associated with its partial funding of the NEIDL. The NIH also issued a record of decision (ROD), which is a concise written record of the NIH's decision based on the EIS. In the case of the NEIDL, the NIH determined in its early 2006 ROD that the NEIDL posed a negligible risk to the community and that the NEIDL would not have a disproportionate impact on low-income and minority populations.

Areas studied as part of the NEIDL EIS include:

- Social resources
- Economic resources
- Environmental justice
- Visual quality
- Wastewater and water resources
- Biological resources
- Air quality
- Noise
- Transportation
- Historic and cultural resources
- Land use
- Cumulative impacts
- Human health and safety

He also discussed key differences and similarities between the NEPA and the Massachusetts Environmental Policy Act (MEPA). In terms of scope, the NEPA analysis was limited to the NEIDL facility, whereas the MEPA analysis included the entire BioSquare Discovery and Innovation Center 2 complex that included the NEIDL facility plus other buildings. Under the NEPA, the NIH is the Federal agency that interprets and administers NEPA regulations; in the State process, the Massachusetts Executive Office of Energy and Environmental Affairs (EOEEA) is the administering agency. Both the NEPA and the MEPA involve extensive interaction with the public and incorporation of resulting public comment.

VII. Review of the BU NEIDL Under the MEPA

Presenter: Deerin Babb-Brott, MEPA Office

Mr. Babb-Brott discussed the purposes and processes of the MEPA and how it has been applied to a review of the BU NEIDL. He pointed out a key distinction between the Federal and State laws: for the NEPA, the EIS is developed by the Federal agency, whereas under the MEPA, the organization proposing the laboratory (the proponent) develops the environmental impact reports (EIRs) pursuant to a scope of work issued by the EOEEA Secretary, which precedes public comment and review.

The two purposes of the MEPA are to (1) ensure that proponents provide meaningful opportunities for public review of potential environmental impacts associated with their proposed activities and (2) require State agencies to study the environmental consequences of their actions, including permitting and financial decisions. The MEPA also requires that State agencies take all feasible measures to avoid or minimize and mitigate damage to the environment by studying alternatives to a proposed project, evaluating respective impacts, and developing enforceable mitigation commitments that become permit conditions for the project if it is permitted.

The MEPA process begins when the proponent files draft and final EIRs for review. Comments from the public and State agencies and relevant information from any other source are considered. A finding of "adequate" or "inadequate" is made; the MEPA does not involve approval or denial of construction. State agencies can act only after the MEPA review has been completed. The MEPA is an informal nonadjudicatory process in the sense that it remains neutral on the merits of the facility; its purpose is to ensure that the potential environmental impacts of the proposed facility are fully disclosed.

In this instance, BU addressed the potential environmental impacts of the NEIDL in a Final EIR, which assessed the potential impact to human health and safety using a worst-case scenario risk assessment

based on the accidental release of anthrax. Although the Final EIR was deemed "adequate," that finding was overturned in State superior court, which remanded the review to the EOEEA Secretary, who issued a requirement for a Supplemental Final EIR to incorporate the superior court's decision. Regarding the issue of the NEIDL's location, the Secretary stated, "The Supplemental [Final EIR] should identify feasible alternative locations for the biocontainment building, including at least one feasible alternative location located in an area less densely populated than the proposed location in Boston's South end. The [Supplemental Final EIR] should evaluate whether the potential public impacts due to the release of a contagious pathogen, including a worst-case scenario, would be materially different if the biocontainment building were located in a feasible alternative location in a less densely populated area." The MEPA has no statutory or working definition of "worst-case scenario."

Mr. Babb-Brott noted that the EOEEA Secretary expects that the NIH, through the BRP, will provide an expert, robust, and objective assessment of the potential risk associated with the proposed NEIDL. The State agency will formally review the submitted NIH materials as part of the Supplemental Final EIR to be submitted by BU.

A. BRP Discussion

In response to a question from Dr. Hamburg about which entity has the authority to approve the NEIDL, Dr. Babb-Brott clarified that the State has jurisdiction—but not approval—over the entire BioSquare 2 project, including the NEIDL; the State approves impacts to traffic and wastewater, but approval of the NEIDL facility itself rests with the City of Boston. Mr. Wheeland clarified that, under the NEPA, the NIH is the agency making the approval decision, and the NIH Director has delegated that authority to the Director of the NIH ORF.

Dr. Holbrook asked a question about the BSL-4 laboratory being built in Galveston, Texas. Dr. Kurilla responded that that laboratory is 85 percent complete. One lesson learned is that community engagement and effective communication with all of the stakeholders involved is essential throughout the process and that the earlier and more productive public engagements return that investment significantly in terms of moving projects forward. Dr. Lipkin explained further that the Galveston site is different from the BU site because there was already a BSL-4 laboratory in place in Galveston, so the lab under construction there is an expansion of a large program that already had community support.

VIII. Boston Municipal Requirements and Safeguards for Biocontainment Laboratories

Presenters: M. Anita Barry, MPH and Roger Swartz, JD, Boston Public Health Commission (BPHC)

A. Regulations and Implementation/Mr. Swartz

Before his formal presentation, Mr. Swartz offered a general comment about the importance of working with the community and the resulting good will that occurs. His presentation focused on the development of regulations, an overview of the regulations, implementation, and lessons learned. The BPHC operates as the board of health for Boston; the director is a member of the mayor's cabinet. The BPHC's Communicable Disease Control Division is responsible for surveillance and control of communicable diseases within the City of Boston.

The purpose of BPHC regulations is to protect the safety and health of the public, laboratory workers, and the environment and to increase public confidence in and awareness about laboratory safety. The goal of BPHC medical surveillance for research laboratories is to enhance safety in laboratory settings, particularly for those working with high-risk agents, and the surrounding communities through early detection and management of specified illnesses. Reporting to the BPHC is mandatory and covers illness, significant exposures, and unexplained absenteeism; Dr. Schwartz provided details of the reporting requirements. In addition, occupational health officers and designees at each site are required

to report specified infections and unusual illnesses to the BPHC, including infections not covered specifically by BPHC guidelines.

A summary of the major concerns that emerged during the public comment period for the BU NEIDL included concern that the regulations would serve as a disincentive for research laboratories in Boston, concern about the burdensome nature of reporting and the need to ensure that reporting requirements would be streamlined and not duplicative, and concern about how to maintain confidential information that could jeopardize public safety as well as concern about protecting proprietary information. Two general comments expressed basic opposition to the BSL-4 work within the City of Boston and interest in increased community involvement in the oversight process.

Mr. Swartz highlighted the transportation plan, since there had been much concern from the community about transportation of agents that would be used in BSL-4 laboratories. A result of a consultative process with other city agencies, the NEIDL staff, and representatives of the transportation vendor is that the BU staff will be putting together more specific requirements about how transportation will be handled; at that point, city agency plans can be reviewed to make sure that the plans are well integrated and that drills can be conducted to test those plans. The BPHC expects that this transportation plan process will be a model for use in reviewing and implementing other plans.

B. Medical Surveillance/Dr. Barry

Dr. Barry discussed the BPHC medical surveillance program as it relates to research in infectious diseases research laboratories. In Boston, both city and State laws and regulations mandate disease reporting. Health care providers, institutions, and research laboratories must report specified diagnoses, either suspected or confirmed, to the BPHC. With regard to research laboratories, the BPHC developed an enhanced medical surveillance program to enhance safety in laboratory settings, particularly those working with high-risk agents, to protect the surrounding community through early detection and management of specified illnesses.

The BPHC medical surveillance program applies to research laboratories that use any of the following organisms: CDC-defined select or overlap agents, NIH Risk Group 4 agents, severe acute respiratory syndrome coronavirus, high-pathogenicity avian influenza virus, vaccinia virus, and mycobacterium TB. More organisms may be added to the list as needed. If a research lab worker develops an illness that could be due to exposure to a high-risk agent used in that lab, the illness must be reported to the BPHC within 1 business day; the BPHC also must be notified if a worker in a research laboratory using a high-risk agent has a significant exposure or if there is any unexplained absenteeism among lab workers.

Key elements of the BPHC surveillance regulations include their applicability to an institution's investigators and day-to-day laboratory managers. Although officials and managers who are responsible for laboratory supervision are educated about the regulations, the BPHC believes that continuing education for individuals who are directly involved in laboratory work is key. That instruction should include education about illness that might be caused by the agents with which they are working, good laboratory practices with an emphasis on infection control and appropriate personal protective equipment, and understanding of postexposure or incident protocols, including how and where to report lab accidents or illness.

Noting that nearly 50 percent of deaths in the United States in the early 20th century were due to infectious diseases and that research has reduced this rate significantly, Dr. Barry stated that continued progress requires continued research. The BPHC understands that individual safety and community safety are key considerations in the planning of research and research facilities, and Dr. Barry observed that a local public health agency is the first and primary responder for incidents in local communities.

C. Inspections/Mr. Swartz

Mr. Swartz explained the inspection requirements for the NEIDL. The BPHC requires at least one inspection per year of BSL-3 facilities and at least two inspections per year of BSL-4 facilities. Inspection

components include review of policies and procedures and onsite documentation, staff interviews to assess whether relevant skills and awareness of personal protective equipment, basic biosafety practices, and evacuation procedures are up to date. As part of the BU NEIDL inspection, the BPHC also will conduct observations of the physical facility and of laboratory practices; inspection protocols are being finalized.

BPHC regulations also require the establishment of a City of Boston Biosafety Committee, which is charged with providing recommendations on all relevant issues to the Executive Director of the BPHC. Issues such as permitting, inspections, and project registrations are expected to arise. The committee will be composed of seven members, including two community residents. One of these committee meetings will be an annual public meeting for which the community will be notified in advance. To ensure that the committee is in a strong position to ensure safety and protection in the laboratory, the chair of the committee will be required to report directly to someone in senior management who is authorized to ensure compliance with all of the terms of the regulations. This committee is being established and will hold its first meeting in late spring 2008.

Other elements of the regulations include a process for lab workers to notify the BPHC of any problems, penalties (ranging from fines to immediate closing of the facility), and development of a training plan. The BPHC has contracted with Emory University to offer basic training and awareness for the city staff; in April 2008 a training assessment will be conducted to identify future training needs.

Mr. Swartz enumerated several lessons learned, including the importance of a transparent process, taking adequate time for the planning phase, coordination, and education and awareness of all stakeholders to make sure that the framing of risk in the community is accurate.

D. BRP Discussion

Dr. Lipkin asked about the 1 business day reporting requirement, integrating efforts with health departments in other cities, and plans to conduct serology on lab workers before and after working at BSL-3 and BSL-4 facilities. Dr. Barry responded that the BPHC believes that the 1 business day reporting requirement is adequate and noted that the BPHC has a 24/7 call-in system for reporting illness. The BPHC communicates routinely with other local health departments and informs relevant health departments of any concerns related to a traveling lab worker. With regard to serology, as part of permitting, each institution is required to submit an occupational health plan to the BPHC; those plans differ by institution and by organisms being studied, and not all institutions plan to obtain baseline serologies. Dr. Barry explained that one issue that has been raised among institutions considering doing serologies is the expense of storing them.

In response to a query from Dr. Kasper regarding whether only researchers and lab workers who are dedicated to a particular lab can work there, Dr. Klempner responded that only full-time, trained BU employees will deal with select agents in the laboratories.

Dr. Klempner explained BU's internal three-step process, which takes place before a project is submitted to the BPHC. This process grew out of more than 400 community meetings that were convened to make the planning process as transparent as possible. The first step is review by the institutional biosafety committee. The second step is disclosure of every project to the internal scientific advisory committee, which is composed of the laboratory chiefs in the building. The third step is disclosure of every project to the external scientific advisory committee, likely in the form of e-mail transmissions due to issues of distance from BU. This three-step process has been put in place to make sure that proposed research projects are considered important, valid, and safe before they are submitted to the BPHC.

In response to Dr. Burke's query regarding final approval for working in the facility vs. final approval for the facility itself, Dr. Swartz responded that the BPHC has authority for the former and that Boston's Inspectional Services Department issues building permits for businesses to operate. Both Boston entities must provide approval—for the physical building and for the work to be conducted within that building—before a research laboratory can become operational.

Dr. Swartz explained that, in time of war or an outbreak somewhere in the world with an unrecognized or new organism, the BPHC has full authority to take any action necessary, within or outside of the regulations already in place for the NEIDL and other similar laboratories.

IX. Legal Proceedings: Federal and State

Presenters: Seth D. Jaffe, JD, MPP, of Foley Hoag LLP, and David W. Lankford, JD, Office of the General Counsel, NIH

A. Federal NEPA Lawsuit/Mr. Lankford

Mr. Lankford explained that three lawsuits have been filed in relation to the funding and construction of the BU NEIDL: a Federal NEPA lawsuit, a complaint with the HHS Office for Civil Rights with a subsequent lawsuit, and a State lawsuit under the MEPA; his presentation would focus on the Federal NEPA lawsuit.

In January 2006, the NIH completed its NEPA review and determined that there was negligible risk to the public posed by the BU NEIDL. In May 2006 several Boston residents and two public interest groups sued the NIH under the NEPA; BU joined the lawsuit as a co-defendant. The plaintiffs asked the court to declare that NIH violated the NEPA and to stop NIH's partial funding of the NEIDL. The plaintiffs alleged that NIH failed to properly assess potential risks of the NEIDL to the public health and failed to consider alternative locations, including less populated areas. However, the heart of the Federal lawsuit is the plaintiff's claims that infectious agents would be released from the NEIDL and would harm the surrounding community. Although the plaintiffs tried to broaden the scope to BSL-3 and below, the court limited the case to BSL-4 agents. The plaintiffs also have raised an EJ claim, arguing that the NEIDL's location will have a disproportionate impact on low-income and minority populations.

Although construction of the NEIDL has been allowed to continue, BSL-4 research will not be conducted until the court decides whether the NIH has complied with the NEPA. If the court determines that the NIH has not complied, the court could deny the conduct of BSL-4 research at the NEIDL pending further environmental review by the NIH; the court also could enjoin use of the rest of the NEIDL, although that result is unlikely because the case concerns BSL-4.

In August 2007, the NIH released the DSRASSA for public comment. Public comment on the DSRASSA included a report from the NRC committee. After receiving the comments and considering them, the NIH decided to perform additional analyses of the potential risks of the NEIDL; the purpose of the BRP is to help the NIH determine what additional analyses, if any, should be performed.

Investigation of the second Federal action—the complaint filed with the HHS Office for Civil Rights—has been postponed pending completion of the NIH's supplementary assessments and the NEPA lawsuit, due to the likelihood that the NIH's analyses of the risks posed by the NEIDL will be relevant to the discrimination complaint.

B. State Court Litigation/Mr. Jaffe

Mr. Jaffe discussed MEPA requirements that are applicable to the NEIDL. State superior court proceedings in July 2006 concluded that the EOEEA Secretary's approval of the Final EIR was arbitrary and capricious; the Massachusetts Supreme Judicial Court affirmed the decision of the superior court in December 2007. The superior court has decided not to rule at this point, primarily because the plaintiffs have not asked for an injunction in the State court proceedings; when the supplement to the final EIR is completed, any of the parties to these proceedings will have the opportunity to return to court at that time.

Mr. Jaffe noted that the heart of a supplemental Final EIR would be whatever supplemental risk assessment was performed by or at the behest of the NIH, so BU made the decision to let that process play out fully before finalizing the State process.

Considerations in the State-level evaluation include the NRC report, and if the concerns expressed in the NRC report are not responded to adequately, those concerns will be brought back before the State court. The court is the ultimate referee and might decide that modeling one worst-case scenario may not be sufficient. Clarification of the distinction between BSL-3 and BSL-4 agents is needed, because there may be confusion on this key point and it will be important for the outcome of the court cases that the risks of this facility and the differences in types of risk be understood and clearly communicated.

Although no due date has been established for submission of the Supplemental Final EIR, once that document has been submitted, the 30-day comment period begins and the Massachusetts EOEEA has 7 days from the close of the comment period to issue a decision.

X. Overview of the DSRASSA for the BU NEIDL

Presenter: Deborah E. Wilson, DrPH, CBSP, Office of Research Services, NIH

Dr. Wilson presented an overview of the DSRASSA, which was initiated because the Federal judge presiding over the NEPA lawsuit requested information regarding impact on the community should an agent, such as ebola virus, be released from the BU NEIDL. Additional evaluations of the two alternative sites in suburban Massachusetts and rural New Hampshire were conducted to further ensure that equal consideration was given to each. Additional risk assessments were performed to investigate the extent to which an exotic disease agent, if accidentally released from a high-biocontainment laboratory, might spread into communities in which the NEIDL might be sited, compare the impacts on the three sites, and determine whether there would be disproportionate health impacts on the three EJ communities surrounding the Albany Street (Boston) NEIDL site. A variety of mechanisms were used to engage the public in the development of the DSRASSA so that the risk assessments would reflect community input and address community concerns.

The DSRASSA contains two primary parts: the qualitative additional site analyses and the quantitative risk assessment evaluations of four complex infectious disease scenarios. Sites selected for comparative analysis were the BU-Albany Street site in Boston, Massachusetts; the BU Corporate Education Center in Tyngsborough, Massachusetts; and the BU Sargent Center for Outdoor Education in Peterborough, New Hampshire. Risk assessment data were derived for three simulated synthetic communities: an urban environment with EJ communities present (Boston), a suburban environment with no EJ communities present (Tyngsborough), and a rural environment with no EJ communities present (Peterborough).

Examination of the suitability of the three sites included consideration of the following points: location of the facility; impact on the visual quality of the site should a building be erected there; impact on historic resources; noise; availability of utilities and impacts on existing utilities; transportation and access; air quality impacts; economics, income, and demographics; and availability of and impacts on health care facilities, social existence, and emergency response services. Other factors evaluated among the three sites were the presence of flood plains, wetlands, riparian areas, and surface waters; impacts on habitat, wildlife and vegetation, and threatened or endangered species; and impacts on agriculture and livestock.

Data collection for the additional site analyses was accomplished via site visits; review of a variety of public documents, master plans, local regulations, covenants, and environmental testing results; interviews at the sites; visits to health care facilities that would serve the site, including interviews with the staff; site plan reviews; and review of utility plans and any other literature and information pertaining to all three sites.

The mechanisms used to engage the public in Boston included a series of community meetings inviting comment. These meetings were advertised in newspaper notices in Spanish, English, Portuguese, and

Chinese. Fliers were posted and made available throughout the potentially affected communities. An e-mail address was established and advertised to receive comments, as was a toll-free telephone number to receive input on what kinds of studies the public would want to see conducted. In addition, the NIH participated in a back-to-school night at a local elementary school near the Albany Street site, handing out notices about the community meetings and obtaining public input about the NEIDL project. The following scenarios were suggested by the public, all of which were incorporated into the DSRASSA:

- A transportation accident with subsequent release of an infectious agent
- Release of a vector-borne disease agent
- Release of an infected arthropod
- A laboratory incident concerning mislabeling of a specimen or stock culture
- Release of a recombinant organism
- A laboratory incident involving ebola virus (information from the community suggested a large knowledge gap about the natural history, pathogenesis, and communicability of Ebola)
- A laboratory incident involving a pox virus (there is a continuing misperception that the NEIDL will be conducting smallpox research; the actual plan is to study the characteristics of smallpox using other agents such as monkeypox)
- An incident involving a school or school-age children
- An incident requiring transport of an infected patient

The four diseases chosen for study were ebola hemorrhagic fever, monkeypox, Brazilian hemorrhagic fever (Sabia virus), and Rift Valley fever. Ebola virus was chosen primarily because the Federal judge was interested in this agent and because of grave public concern. Monkeypox was chosen as a surrogate for smallpox because it closely resembles smallpox and because of a remaining fear and concern about the 2003 outbreak of monkeypox in six Midwestern States. Sabia virus is a representative of the arenavirus group, the New World hemorrhagic fever viruses; very little is known about this virus, and there are two known human cases that have originated from a laboratory, one of which was a researcher at Yale University that was highly publicized throughout the northeastern United States when it occurred. Rift Valley fever virus was included because of ongoing outbreaks in Kenya, Somalia, and Tanzania; humans are highly susceptible to this virus, it has caused many laboratory-acquired infections, and some scientists worry that it could reach the United States.

A “worst case” was defined functionally as a low-probability event with a high-magnitude outcome, which at the NIH was translated to a release of an agent from a BSL-4 containment laboratory resulting in one or more index cases through which community exposure could occur.The risk assessment scenarios were based on available science, recommended public health practice, and knowledge of laboratory “near-misses.” Information and data were used in scenario development in a way that overstated the risks in order to support a worst-case analysis approach. Where information was not available, decisions were made that would maximize the risks and negative outcomes with respect to the community, again for the purpose of a worst case scenario. The same infectious disease parameters were applied across all three communities, and the scenarios were designed to force an infection—at least one index case and in most cases a secondary case—for comparisons among the communities. In developing the models, probabilities of disease occurrence were assigned to events that have not occurred in nature. No additional public health interventions—such as insect repellants or immunizations—were included in the simulations. The risk assessments were designed to detect differences in risk among the three communities should a release occur; they were not designed to determine whether there were risks caused by the building itself or evaluate intervention strategies.

A model was chosen that would simulate the actual communities as closely as possible, including population, demographics, geography, employment, characteristics of local households, and recreational activities. The model needed to be adaptable to different diseases and different infectious agents and be sensitive to population density if that was important in the disease transmission of a particular disease. The model also needed to accurately represent the actual populations so as to be able to investigate the role of social interactions in the transmission of the selected diseases.

Two agent-based modeling techniques were used: the Agent-Based Explicit Spatial and Temporal (A-BEST) model and the Multi-Layer Agent-Based Simulation Tool (MLAB-ST) model. The A-BEST model provided synthetic communities that were statistically indistinguishable from the actual communities. Four exotic infectious diseases were investigated. It provided an adaptable environment for the worst-case analyses, allowed use of an aggregate exposure approach, and allowed comparisons with highly contagious disease. The results included who gets infected, when they become infected, where they get infected, and the individual outcome for the modeling agent. The MLAB-ST model was applied to the vector-borne disease only and used multilayered maps to provide the model structure. This model allowed greater consideration of vector biology, tracking of the disease beginning with one infected individual bitten by one mosquito, and evaluation in a constrained environment.

The DSRASSA was prepared as a public document consistent with the NEPA, not as a scientific report, and thus was written at an eighth-grade reading level, and contained many photographs, graphics, charts, and tables to assist the public in reviewing its content. Appendixes presented summary statistics, maps of discrete time and spatial spread of disease, and additional detail about the architecture of the more complicated models. Conclusions reported in this document were based on the qualitative analyses that incorporated data from the risk assessments. This study was conducted as a result of the Federal NEPA lawsuit and was conducted after the site selection, after the ROD was issued, and after building construction had begun.

XI. Discussion With NRC Committee Members

Discussants: Gigi Kwik Gronvall, PhD, University of Pittsburgh Medical Center, and Gary Smith, DPhil., University of Pennsylvania School of Veterinary Medicine

A. Introduction/Dr. Gronvall

The NRC committee review of the DSRASSA included several criticisms, and the BRP had an opportunity at this meeting to discuss those criticisms with two members of the NRC committee. The NRC committee's review of the DSRASSA addressed questions pertaining solely to its scientific adequacy—determining whether the scientific analyses in the DSRASSA were sound and credible, whether representative worst-case scenarios had been used, and whether there was a greater risk to public health and safety from locating the facility in one or another of the three proposed locations. This technical review of the DSRASSA was not a commentary on whether the laboratory was necessary or on the kind of research that was proposed to be conducted there.

B. NRC Committee Findings/Drs. Gronvall and Smith

Defining "sound" as "free from error" and "credible" as "worthy of belief" and analyzing "appropriate" as the kind, quality, and quantity of information, the NRC committee found that the DSRASSA was neither sound nor credible, had neither adequately nor thoroughly identified worst-case scenarios, and did not contain an appropriate level of information to compare the risks associated with alternative locations. The criteria used were similar to those ordinary criteria for evaluating a paper presented for publication to a scientific journal or a grant proposal presented for competitive funding.

Drs. Gronvall and Smith discussed agent and release scenario concerns and modeling methodology concerns. In particular:

- It was not clear why the agents selected for the risk assessment did not have higher transmission probabilities that would highlight the differences among the suburban, urban, and rural populations and could lead to large infection rates.
- The analysis could have been improved by the selection of an agent that was vector-borne and that was more relevant to an urban population, for example, an agent carried by rats or mice rather than cattle.

- It was not clear whether the selected worst-case scenarios could appropriately be called "worst cases." The NRC committee suggested other scenarios, including equipment failure, site personnel security failure, failure of procedures, or a malevolent action.
- EJ issues were not addressed.
- Risk communication within the report included statements about the risks being negligible or vastly overstated, which might appear dismissive of public concerns, especially when the statements were not accompanied by evidence to exemplify those risks.
- It was not clear why diseases with low transmission potential but high case fatality rates constituted a worst case, rather than diseases with a high transmission potential but a lower case mortality rate.
- The failure to present a satisfactory or, in some instances, any rationale for the choices applied throughout the DSRASSA was a recurrent problem, and background information was frequently presented declaratively.
- Although the agent-based modeling methodology was appropriate, it was not transparent in terms of clearly describing the assumptions that underpinned the models.
- While understanding that analyses are difficult and sometimes impossible to carry out formally, the NRC committee believed that the DSRASSA should have included at least a qualitative discussion of the uncertainties inherent in the modeling process and in the interpretation of model behavior.
- The results of the modeling did not facilitate decisionmaking; although the models might have been good models, the text of the DSRASSA provided no grounds to make that judgment.
- Opportunities were missed in the DSRSSA. For example, agent-based models are ideal for examining consequences of infection in populations that differ with respect to their contact structure and their susceptibility to infection, disease, and violence; this would have been one way to examine EJ issues.

C. BRP Discussion

Dr. Amy Patterson asked whether the NRC committee members understood that they were reviewing a document that was prepared to answer a separate set of questions for the Federal court and that was not prepared to address the issues at the State level and that they were evaluating a subset of a universe of documents that explored potential risks. Dr. Smith responded that the NRC committee confined itself to answering a charge created by the State. The NRC committee was not given much background as to why this document was developed, and the NRC committee's responses and critique of the DSRASSA was based entirely on the charge from the State.

XII. Environmental Equity and Health

Presenter: Mary E. Northridge, PhD, MPH, Columbia University and *American Journal of Public Health*

Dr. Northridge explained that, in this case, EJ relates to the inequitable burden on African Americans and residents of modest economic means. The EJ movement comes from the tradition of the Civil Rights Movement and focuses on living and working conditions and quality of life in communities that have high disease burdens. "Environmental racism" is the charge that community groups might render, whereas "environmental equity and health" is the goal of society.

She suggested some questions for the BRP to ask during its deliberations, including the nature of community or citizen participation; how a transparent, democratic, ongoing process of citizen and community participation can best be ensured; the role of the NEIDL's mission in building or contributing to a civil society and eliminating social disparities in health; and how city, State, and Federal agencies can work together to advance oversight toward EJ through interdisciplinary engagement.

Dr. Northridge concluded with a quote from Steve Wing, who works on EJ issues in North Carolina: "The environmental justice movement represents community action to oppose racial and economic inequities in the burden of environmental health hazards. Bringing together traditions of labor, civil rights, economic justice, and environmental and antiwar organizations, the environmental justice movement mobilizes to improve living and working conditions and quality of life in communities that have high disease rates and poor access to medical care and health-promoting services."

XIII. Public Comment

Dr. Mahmoud requested that public comments be limited to 3 minutes each; those wishing to make remarks longer than 3 minutes were requested to provide those remarks in writing to the NIH for inclusion in the official record.

Public attendees offered no comments.

XIV. BRP Discussion

Dr. Burke asked whether the BRP is responsible for considering BSL-3 issues in addition to BSL-4 issues. Dr. Patterson responded that the primary focus of the Federal court inquiries was the BSL-4 level; however, the State-level concerns are much broader.

In response to Dr. Hamburg's query about documents that the BRP is expected to produce, Dr. Patterson explained that the BRP would review the DSRASSA as it currently exists, the concerns of the NRC committee, the concerns expressed in public comments, and the concerns of the State. The BRP then will advise the NIH about the scope of a revised draft supplemental report and what form it should take.

XV. Next Steps

Dr. Mahmoud explained that the BRP's next steps are to conduct an in-depth analysis of and solicit public comments on the DSRASSA, including the NRC committee's analysis, and conduct an in-depth analysis of the NEPA requirements. He noted that the BRP is a working group of the ACD, which means that the BRP will report to the ACD during public meetings. Therefore, the ACD's consideration of the BRP's recommendations will be transparent and accessible to the public.

XVI. Adjournment

Dr. Mahmoud thanked the BRP members and the NIH staff and adjourned the meeting at 2:15 p.m. on March 13, 2008.

Signed by Dr. Adel Mahmoud, Chair of the NIH Blue Ribbon Panel on 6/30/08
Signed by Dr. Amy Patterson, Executive Secretary to the NIH Blue Ribbon Panel on 7/1/08

[Note: Actions approved by the BRP are considered recommendations to the ACD; therefore, actions are not considered final until approved by the ACD. Additional information about this Blue Ribbon Panel can be found at http://www.nih.gov/about/director/acd/index.htm.]

Attachment I
Blue Ribbon Panel Roster

Chair

Mahmoud, Adel, MD, PhD
Professor of Molecular Biology
Woodrow Wilson School of Public and International Affairs
Princeton University

Members

Burke, Donald S., MD
Dean
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Associate Vice Chancellor for Global Health
Director, Center for Vaccine Research
Jonas Salk Chair in Global Health
University of Pittsburgh Medical School

Eubank, Stephen, PhD
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Deputy Director, Network Dynamics and Simulation Science Laboratory
Adjunct Professor of Physics
Virginia Polytechnic Institute and State University

Freimuth, Vicki S., PhD
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Center for Health and Risk Communication
University of Georgia

Friedman-Jiménez, George, MD
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Bellevue/New York University Occupational and Environmental Medicine Clinic
Bellevue Hospital Center

Hamburg, Margaret A., MD
Senior Scientist
Nuclear Threat Initiative

Holbrook, Karen A., PhD
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Speakers

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Executive Office of Environmental Affairs

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Communicable Disease Control Division
Boston Public Health Commission

Gronvall, Gigi Kwik, PhD
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CAPT US Public Health Service
Director, Division of Occupational Health and Safety
Office of Research Services
Office of the Director, NIH
U.S. Department of Health and Human Services

Zerhouni, Elias A., MD
Director
National Institutes of Health
U.S. Department of Health and Human Services

Attachment II
Abbreviations and Acronyms

A-BEST model	Agent-Based Explicit Spatial and Temporal model
ACD	Advisory Committee to the Director, NIH
Blue Ribbon Panel	NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Diseases Laboratories at the Boston University Medical Center
BPHC	Boston Public Health Commission
BRP	Blue Ribbon Panel
BSL	biosafety level
BU	Boston University
CDC	Centers for Disease Control and Prevention
DHHS or HHS	U.S. Department of Health and Human Services
DSRASSA	Draft Supplementary Risk Assessments and Site Suitability Analyses
EIR	environmental impact report
EIS	environmental impact statement
EJ	environmental justice
EOEEA	Executive Office of Energy and Environmental Affairs, Commonwealth of Massachusetts
HSPD	Homeland Security Presidential Directive
IBC	institutional biosafety committee
MEPA	Massachusetts Environmental Policy Act
MDR TB	multidrug-resistant tuberculosis
MLAB-ST model	Multi-Layer Agent-Based Simulation Tool model
NBL	National Biocontainment Laboratory
NEIDL	National Emerging Infectious Diseases Laboratories
NEPA	National Environmental Policy Act
NIAID	National Institute of Allergy and Infectious Diseases, NIH
NIH	National Institutes of Health, DHHS
NRC	National Research Council
OD	Office of the Director, NIH
ORF	Office of Research Facilities Development and Operations, OD, NIH
RBL	Regional Biocontainment Laboratory
RCEs	Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases
ROD	record of decision
XDR TB	extensively drug-resistant tuberculosis